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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,613	03/07/2001	William F. Northrup III	M104.120.102	7496

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EXAMINER

ODLAND, KATHRYN P

ART UNIT PAPER NUMBER

3743

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/800,613

Applicant(s)

NORTHROP ET AL.

Examiner

Kathryn Odland

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 6, 7 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-26 and 30-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Specification***

The amendments to the title and abstract are acknowledged.

### ***Election/Restrictions***

1. Claims 6-7 and 27-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group and Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.
2. Applicant's election with traverse of Group I and Species I in Paper No. 8 is acknowledged. The traversal is on the ground(s) that there is no serious burden on the examiner. This is not found persuasive because the species are structurally different and the method could be performed with another apparatus and vice versa since the sequential steps are not required for the apparatus.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
4. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The distance has not been identified with respect to any direction. It is unclear if the distance is measured in the bent position, the open

position, or both closed and open positions. Further, it is unclear how the measurement is taken. Any art rejection will be as best understood.

5. Claim 4 recites the limitation "the lumen" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no prior recitation of a lumen.

6. Claim 16 recites the limitation "the lumen" in line 1. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 17 recites the limitation "the lumen" in line 1. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 20 recites the limitation "the spacing elements" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim. There is no prior recitation of spacing elements only means for spacing.

9. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 recites means for everting and means for spacing that are disposed on opposite ends of the staple. It is unclear as to what is disposed on opposite ends of the staple. It is unclear if it is intended that the spacing means are disposed on an opposite end from the everting means with respect to the staple body or if the spacing means and everting means together on an opposite side of the staple, etc. Further it is unclear if this opposed position is in the unbent position, bent position, both, etc. Any art rejection will be as best understood.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-5, 8-13, 15-17, 19-26, 30, and 32-35 are rejected under 35

U.S.C. 102(b) as being anticipated by Miller in US Patent No. 2,254,620.

Regarding claim 1, Miller discloses a surgical staple for use in creating an everted anastomosis of at least two anatomical structures, the staple having a staple body (via elements such as 10, 11, 8, 9, etc.) constructed for bending and at least two everting elements (such as 8, 9 / (30, 31), etc.) connected to the staple body, the everting elements (8, 9) protruding from the staple body, the staple body and the everting elements being constructed and arranged so that when the staple body is bent around cut ends of the anatomical structures, the everting elements are in an apposed relationship and the inner layers of the anatomical structures are held together between the everting elements to form the everted anastomosis, as recited on page 1 and seen in figures 1-5.

Regarding claim 2, Miller discloses that as applied to claim 1, as well as, at least two spacing elements (19, 20) connected to the staple body, the spacing elements being constructed and arranged so that when the staple body is bent around the cut ends of the anatomical structures, the spacing elements are in an

apposed relationship and the cut ends of the anatomical structures are held together between the spacing elements, as recited on page 1 and seen in figure 2.

Regarding claim 3, Miller discloses that as applied to claim 2, as well as, a distance between the apposed spacing elements (19, 20) that is less than the distance between the apposed everting elements (8, 9), as seen in figures 2 and 4.

Regarding claim 4, Miller discloses that as applied to claim 2, as well as, apposed everting elements (8, 9) that are closer than the apposed spacing elements (19, 20) to a lumen of the anastomosed anatomical structures, as seen in figures 2 and 4 where the cut 25 can be considered a lumen.

Regarding claim 5, Miller discloses that as applied to claim 2, as well as, apposed spacing elements (19, 20) that define an inner radius of the bent staple and the apposed everting elements (8, 9) define an outer radius of the bent staple, the radii being taken from the bend in the staple, as seen in figure 4.

Regarding claim 8, Miller discloses that as applied to claim 2, as well as, one of the spacing elements (19, 20) that is disposed along the staple body and the other of the spacing elements is disposed adjacent the staple body, as seen in

figures 1-4, wherein one can be considered along and the other can be considered adjacent.

Regarding claim 9, Miller discloses that as applied to claim 2, as well as, spacing elements (19, 20) that are disposed closer to the middle of the staple than the everting elements (8, 9), as seen in figure 2, where the middle is considered at element 10 in figure 2.

Regarding claim 10, Miller discloses that as applied to claim 1, as well as, everting elements (8, 9) that are disposed at the very ends of the staple body, as seen in figure 2, where the reference numerals 8 and 9 are shown at the very ends and the middle is considered at numeral 10.

Regarding claim 11, Miller discloses that as applied to claim 1, as well as, a penetrating element (such as 21) constructed to penetrate the ends of the anatomical structures when the everting elements are in the apposed relationship, as recited on page 1 and seen in figures 1-5.

Regarding claim 12, Miller discloses that as applied to claim 11, as well as, a penetrating element (such as 21) that is disposed at one end of the staple body, as seen in figure 2, where one end is considered at elements numbers 14 and 15 and the other is at element numbers 21 and 23.

Regarding claim 13, Miller discloses that as applied to claim 1, as well as everting elements (8, 9) that are offset from each other transversely with respect to the staple body, as seen in figures 1-5, where the transverse direction has not been established. However, the elements 8 and 9 are offset with respect to each other depending on their bent position.

Regarding claim 15, Miller discloses that as applied to claim 13, as well as, one of the everting elements that moves laterally with respect to the staple body as the staple is bent, such that the direction of closure of the staple is at an angle to the staple body, as seen in figures 1-5, wherein one side can be bent toward the other.

Regarding claim 16, Miller discloses that as applied to claim 1, as well as, a staple body that is outside the lumen of the anastomosed anatomical structures when the everting elements are apposed, as seen in figures 1-5.

Regarding claim 17, Miller discloses that as applied to claim 1, as well as, a lumen (25) of the anastomosed anatomical structures that is free of exposure to the staple and to cut tissue edges of the anatomical structures, as seen in figure 18.



Regarding claim 19, Miller discloses a surgical staple for use in creation of an everted anastomosis between at least two anatomical structures, the staple having means for bending (at 10, 11) and means (8, 9) for everting connected to and protruding from the means for bending, the means for bending (10, 11) and the means for everting (8, 9) being constructed and arranged so that when the means for bending (10, 11) is bent around cut ends of the anatomical structures, the means for everting (8, 9) forms an apposed relationship and the inner layers of the anatomical structures are held together between the means for everting (8, 9) to form the everted anastomosis, as recited on page 1 and seen in figures 1-5.

Regarding claim 20, Miller discloses that as applied to claim 19, as well as, means for spacing (19, 20) connected to the staple body (10, 11, 8, 9, etc.), the means for spacing (19, 20) being constructed and arranged so that when the staple body is bent around the cut ends of the anatomical structures, the means for spacing are in an apposed relationship and the cut ends of the anatomical structures are held together between the spacing elements (19, 20).

Regarding claim 21, Miller discloses that as applied to claim 19, as well as, means for everting (8, 9) and means for spacing (19, 20) that are disposed on opposite ends of the staple, as seen in figure 4, where one end of the staple is considered at numeral 10 and the other is considered at 8, 9, 19, 20.

Regarding claim 22, Miller discloses a surgical staple constructed to join at least two anatomical structures, the staple having a first everting platform (8) disposed at a first end of the staple, the first everting platform being centered at the first end of the staple, as seen in figures 1-5; a second everting platform (9) disposed at a second end of the staple, the second everting platform being connected at one end thereof to the second end of the staple, the first and second everting platforms being constructed to form an everted anastomosis of the anatomical structures, as stated on page 1 and seen in figures 1-5; a first spacing (such as 19) element disposed at the first end of the staple, the first spacing element being disposed adjacent (defined as near/close to) the longitudinal axis of the staple (the longitudinal axis considered to run along element 9); a second spacing element (20) disposed at the second end of the staple, the second spacing element (20) being disposed along the longitudinal axis of the staple, as seen in figure 1; and a penetrating element (such as 21) for penetrating the anatomical structures, the penetrating element (such as 21) being disposed at the first end of the staple along (close to) the longitudinal axis of the staple, as seen in figures 1-4.

Regarding claim 23, Miller discloses that as applied to claim 22, as well as, a staple is that constructed to bend to a closed configuration in which the second everting platform is disposed parallel to the first everting platform and in which the first and second everting platforms are disposed on the same side of the

penetrating element, as seen in figure 4, where the same side is considered to be at the penetrating element and the opposite side is considered at numeral 10.

Regarding claim 24, Miller discloses that as applied to claim 23, as well as, in a closed configuration the first and second spacing elements are apposed, as seen in figure 4.

Regarding claim 24, Miller discloses that as applied to claim 24, as well as, in a closed configuration the first and second spacing elements and the penetrating element define an inner radius of the staple; further wherein in the closed configuration the first and second everting platforms define an outer radius of the staple, as seen in figure 4.

Regarding claim 26, Miller discloses that as applied to claim 23, as well as, in the closed configuration a staple that is bent into a "U" shape to form two legs and a bend, the legs of the staple being offset from each other in two dimensions, as seen in figure 4.

Regarding claim 30, Miller discloses a device for use in creating an anastomosis of two anatomical structures, the anastomosis defining a central lumen (25), the device having penetration structure (such as 21, 23, etc) for penetrating and holding both anatomical structures at the anastomosis; and an eversion structure

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(8, 9) for everting an end of at least one of the anatomical structures, the eversion structure being disposed closer to the lumen of the anastomosis than the penetration structure, the eversion structure being constructed to accommodate the anatomical structures, as stated on page 1 and seen in figures 1-5, where the lumen is considered to be near numeral 10 in figure 4, where the 25 slits, thus the elements 8 and 9 are closer than 21 and 23, etc.

Regarding claim 32, Miller discloses that as applied to claim 30, as well as, a spacing structure (19, 20) for providing space within the eversion structure to minimize tissue necrosis in the anatomical structures, as seen in figure 4.

Regarding claim 33, Miller discloses that as applied to claim 30, as well as, a device that is a surgical staple, further wherein the penetration structure defines an inner radius of the staple and the eversion structure defines an outer radius of the staple, placement of the inner radius and outer radius causing the staple to be excluded from the lumen of the anastomosis, as stated on page 1 and seen in figures 1-5.

Regarding claim 34, Miller discloses that as applied to claim 30, as well as, a device that is a surgical staple having a staple body, further wherein the eversion structure comprises two everting platforms (8, 9) protruding from the staple body, as stated on page 1 and seen in figures 1-5.

Regarding claim 35, Miller discloses that as applied to claim 30, as well as, a device that is an everting surgical staple, the everting surgical staple being in combination with at least one non-everting surgical staple to form the anastomosis, as discussed on page 1 and seen in figures 1-5.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 14, 18, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller in US Patent No. 2,254,620.

Miller discloses the invention as applied to claims 1, 13 and 30. However, Miller does not explicitly recite an end of one of the everting elements that is aligned with the staple body; further wherein one other of the everting elements is centered on the staple body or a staple that is formed of a memory metal such that at a crimping tool is unnecessary to create the anastomosis. On the other hand, given the unclarity what is intended to be the center of the staple body, it is within the scope of the invention depending on the orientation to have the everting elements centered on the staple body. Further, shape memory material is extremely well known in the art, and it would be obvious to one with ordinary

skill to modify the invention of Miller to be of shape memory material for the purpose of eliminating the need for manual crimping.

**Conclusion**

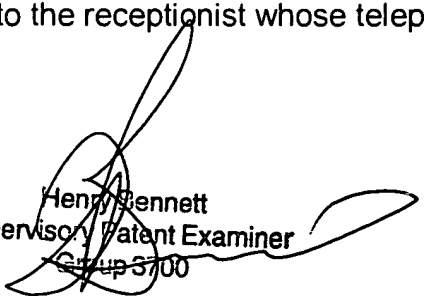
14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 5,993,468; US Patent No. 5,957,938; US Patent No. 5,263,973; US Patent No. 5,171,252; US Patent No. 4,983,176; US Patent No. 4,006,747; US Patent No. 3,378,010; US Patent No. 3,273,562; US Patent No. 3,068,870; and US Patent No. 2,910,067.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO

  
Henry A Bennett  
Supervisory Patent Examiner  
Group 3700